

## WHAT IS CLAIMED IS:

1. A method of preparing a deformable syntactic foam for the delivery of a compound or chemical, the method comprising:

- 5 a) mixing together one or more homopolymer resins, one or more binders, and one or more stabilizers to form a blended mixture having a LOD of from about 1 % to about 10%; and
- d) reacting said blended mixture with one or more organic solvents under conditions of high shear at temperatures of from about 10° C to about 25°C until a foam composition is formed wherein said foam composition is deformable to the touch.

- 10 2. The method according to claim 1 wherein said mixture in step (a) further comprises a particulate substance.

3. The method according to claim 2 wherein said particulate substance is substantially spherical.

- 15 4. The method according to claim 3 wherein said particulate substance is a plurality of microspheres.

5. The method according to claim 4 wherein during the reaction in step (6) the LOD is checked intermittently until the LOD of the reacted mixture is from about 2 percent to about 25 percent.

- 20 6. The method according to claim 5 comprising a further step of separating said syntactic foam into particles.

7. The method according to claim 6 wherein said syntactic foam is lyophilized or freeze dried before separating said syntactic foam into particles.

8. The method according to claim 7 wherein said further step of separating comprises milling the foam.

9. The method according to claim 8 wherein said step of separating further comprises a drying step at from about 25°C to about 60°C.
10. The method according to claim 9 wherein the approximate diameter of said particles is about 1000µm.
11. The method according to claim 9 wherein the approximate diameter of said particles is less than about 1000µm.
12. The method according to claim 7 wherein said step of separating is preceded by a step of treating said syntactic foam to make it rigid.
13. The method according to claim 12 wherein said step of treating said syntactic foam to make rigid comprises contacting said syntactic foam with a cryogenic fluid.
14. The method according to claim 13 wherein said cryogenic fluid is selected from the group consisting of liquid nitrogen and liquid carbon dioxide.
15. The method according to claim 14, wherein the approximate diameter of said particles is about 1000µm.
16. The method according to claim 14 wherein the approximate diameter of said particles is less than about 1000µm.
17. The method according to claim 6 wherein the particles are subsequently molded into a shaped composite.
18. The method according to claim 17 wherein the shape of the shaped composite is selected from the group of shapes consisting of round, triangular, rectangular, polygonal, cylindrical, oval, oblong, capsule, tablet and caplet.
19. The method according to claim 18 wherein said stabilizer is silicic anhydride.
20. The method according to claim 19 wherein said organic solvent is 2-propanol.

21. The method according to claim 20 wherein the homopolymer resin is a carboxyvinyl polymer.
22. The method according to claim 21 wherein the microspheres are selected from the group consisting of silica, sucrose, glucose, lactose, dextrose, sorbitol, mannitol, xylitol, dextrates, poly(lactic acid), poly(glycolic acid), poly(glycolic acid-co-lactic acid), poly( $\epsilon$ -caprolactone), poly(malic acid), cellulose, microcrystalline cellulose, metal, glass and small beads.
23. The method according to claim 22 wherein the microspheres are cellulose microspheres.
24. The method according to claim 23 wherein the blended mixture further comprises a binder.
25. The method according to claim 24 wherein the binder is selected from the group consisting of high molecular weight polysaccharide, xanthan gum, d- $\alpha$  - tocopherol polyethylene glycol 1000 succinate, starch NF, povidone, copolyvidone NF, polyvinyl alcohols, glyceryl behenate, xanthan gum, polyethelene glycols, polyethelene oxides, cellulose binders, hydroxypropyl Methylcellulose USP and hydroxyethyl Cellulose NF.
26. The method according to claim 25 wherein the binder is a high molecular weight polysaccharide
27. The method according to claim 26 wherein the high molecular weight polysaccharide is Xanthan gum.
28. The method according to claim 27 wherein the xanthan gum is d- $\alpha$  - tocopherol polyethylene glycol 1000 succinate.
29. A method of manufacturing a pharmaceutical carrier, the method comprising the steps of:

- a) mixing together:
- i) one or more pharmaceutically acceptable homopolymer resins;
  - ii) one or more pharmaceutically acceptable binders;
  - iii) pharmaceutically acceptable microspheres, and
  - iv) one or more pharmaceutically acceptable stabilizers to form a blended mixture having an LOD of from about 1% to about 10%;
- b) reacting said blended mixture with one or more pharmaceutically acceptable organic solvents under conditions of high shear at temperatures of from about 10° C to about 25°C until a foam composition is formed wherein said foam composition is deformable to the touch; and
- c) reducing the size of the deformable syntactic foam to permit reassembly into a shaped composite.

30. The method according to claim 29 wherein said deformable syntactic foam is reduced in size by drying (LOD less than about 5%) and then milling.

31. The method according to claim 30 wherein said stabilizer is silicic anhydride.

32. The method according to claim 31 wherein said organic solvent is 2-propanol.

33. The method according to claim 32 wherein the homopolymer resin is a carboxyvinyl polymer.

34. The method according to claim 33 wherein the microspheres are selected from the group consisting of silica, sucrose, glucose, lactose, dextrose, sorbitol, mannitol, xylitol, dextrans, poly(lactic acid), poly(glycolic acid), poly(glycolic acid-co-lactic acid), poly( $\epsilon$ -caprolactone), poly(malic acid), cellulose, microcrystalline cellulose, metal, glass and small beads.

35. The method according to claim 34 wherein the microspheres are cellulose microspheres.
36. The method according to claim 35 wherein the blended mixture further comprises a binder.
- 5 37. The method according to claim 36 wherein the binder is selected from the group consisting of high molecular weight polysaccharide, xanthan gum, d-  $\alpha$  - tocopherol polyethylene glycol 1000 succinate, starch NF, povidone, copolyvidone NF, polyvinyl alcohols, glyceryl behenate, xanthan gum, polyethelene glycols, polyethelene oxides, cellulose binders, hydroxypropyl Methylcellulose USP and hydroxyethyl Cellulose NF.
- 10 38. The method according to claim 37 wherein the binder is a high molecular weight polysaccharide
39. The method according to claim 38 wherein the high molecular weight polysaccharide is Xanthan gum.
- 15 40. The method according to claim 39 wherein the xanthan gum is d-  $\alpha$  - tocopherol polyethylene glycol 1000 succinate.
41. A pharmaceutical composition comprising a pharmaceutical and a pharmaceutical carrier wherein said pharmaceutical carrier is prepared in accordance with the method of claim 29.
- 20 42. The composition according to claim 41 wherein the pharmaceutical is selected from the group consisting of human and veterinary medicines.
43. The composition according to claim 42 wherein the pharmaceutical active is selected from the group of pharmaceuticals having one or more active ingredients selected from the group consisting of Acarbose, Acetaminophen/Codeine, Albuterol, Alendronate, Allopurinol, Alprazolam, Amitriptyline, Amlodipine,
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Amlodipine/Benazepril, Amoxicillin, Amoxicillin/Clavulanate, Amphetamine Mixed Salts, Aspirin, Atenolol, Atorvastatin, Azithromycin, Beclomethasone, Benazepril, Bisoprolol/HCTZ, Brimonidine, Carbidopa-Levodopa, Calcitonin, Carisoprodol, Carvedilol, Cefprozil, Cefuroxime, Celecoxib, Cephalexin, Cetirizine, Ciprofloxacin, Cisapride, Citalopram, Clarithromycin, Clonazepam, Clonidine, Clopidogrel, Clotrimazole/Betamethasone, Cyclobenzaprine, d-phenylalanine amino acid derivative, Diazepam, Misoprostol, Digoxin, Divalproex, Donepezil, Doxazosin, Enalapril, Erythromycin, Estradiol, Ethinyl Estradiol / Norethindrone, Famotidine, Felodipine, Fexofenadine, Fexofenadine / Pseudoephedrine, Fluoxetine, Fluticasone Propionate, Fluvastatin, Fluvoxamine, Fosinopril, Furosemide, Gemfibrozil, Glimepiride, Glyburide, Granisetron, Guaifenesin / Phenylpropanolamine, Hydrochlorothiazide, Hydrocodone w/APAP, Ibuprofen, Ipratropium, Ipratropium / Albuterol, Irbesartan, Isosorbide Mononitrate, Lansoprazole, Latanoprost, Levofloxacin, Levonorgestrel/Ethinyl Estradiol, Levothyroxine, Lisinopril, Lisinopril/HCTZ, Loratadine, Loratidine/Pseudoephedrine, Lorazepam, Losartan, Losartan/HCTZ, Lovastatin, Mateglinide, Mesalamine, Methylprednisolone, Metoprolol, Miglitol, Mometasone, Montelukast, Morphine, Mupirocin, Naproxen, Nisoldipine, Nitrofurantoin, Nizatidine, Ofloxacin, Olanzapine, Ondansetron, Oxaprozin, Oxycodone, Oxycodone/APAP, Paroxetine, Penicillin VK, Phenytoin, Potassium Chloride, Pramipexole, Pravastatin, Prednisone, Promethazine, Propoxyphene N/APAP, Propranolol, Quetiapine, Quinapril, Raloxifene, Ramipril, Ranitidine, Repaglinide, Risperidone, Rofecoxib, Salmeterol, Sertraline, Sildenafil, Simvastatin, Sotalol, Sumatriptan, Tamoxifen, Tamsulosin, Temazepam, Terazosin, Terbinafine, Tobramycin/Dexamethasone, Tolterodine, Tranlycypromine, Trazodone, Triamterene/HCTZ, Troglitazone, Valsartan, Venlafaxine, Warfarin, Zafirlukast, and Zolpidem.

44. The composition according to claim 42 wherein said pharmaceutical active is selected from the group consisting of abacavir, amprenavir, staviudine, zalcitabine,

didanosine, delavirdine, efavirenz, hydroxyurea, indinavir, lamivudine, lopinavir, nelfinavir, nevirapine, ritonavir, saquinavir and zidovudine.

45. The composition according to claim 42 wherein said pharmaceutical active is a cyclooxygenase inhibitor.
46. The composition according to claim 45 wherein the cyclooxygenase inhibitor is COX-2.
47. The composition according to claim 46 wherein the COX-2 cyclooxygenase inhibitor is celecoxib or rofecoxib.
48. The composition according to claim 41 comprising a further step of applying a coating agent to the foam before the size reduction step (c).
49. The composition according to claim 41 wherein the size reduced foam is molded into a shaped composite.
50. The composition according to claim 49 wherein a coating agent is applied to the size reduced foam after it is molded into a shaped composite.
51. The composition according to claim 50 wherein the shape of the shaped composite is selected from the group of shapes consisting of round, triangular, rectangular, polygonal, cylindrical, oval, oblong, capsule, tablet and caplet.
52. The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is in interstices between said microspheres.
53. The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is non-covalently bound to said microspheres.
54. The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is covalently bound to said microspheres.

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55. The composition according to claim 41 wherein the pharmaceutical or pharmaceutical active is contained within said microspheres.
56. The composition according to claim 41 wherein the pharmaceutical is active or inactive metabolites of active pharmaceutical ingredients or salts of the metabolites of active pharmaceutical ingredients.
57. The composition according to claim 41 wherein the pharmaceutical is a pro-drug which after oral administration generates active or inactive metabolites.
58. The composition according claim 41 wherein the pharmaceutical is as a precursor which after oral administration generates active or inactive metabolites.
59. The composition according claim 41 wherein the said pharmaceutical is prepared so as to become systemically available over a period of not less than two hours after administration to a human or other mammal.
60. The composition according to claim 41 wherein said pharmaceutical composition is a time-release preparation.
61. The composition according to claim 60 wherein said pharmaceutical elicits pharmacological or therapeutic activity.